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SERIAL NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTORNEY DOCKET NO.
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1011-0117

EXAMINER	
NILAND, P	
ART UNIT	PAPER NUMBER
1511	14

DATE MAILED: 01/17/97

Below is a communication from the EXAMINER in charge of this application

COMMISSIONER OF PATENTS AND TRADEMARKS

ADVISORY ACTION

☒ THE PERIOD FOR RESPONSE:

- a) ☒ is extended to run \_\_\_\_\_ or continues to run 2 months from the date of the final rejection *filing the Notice of Appeal.*
- b) ☐ expires three months from the date of the final rejection or as of the mailing date of this Advisory Action, whichever is later. In no event however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition, and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

☐ Appellant's Brief is due in accordance with 37 CFR 1.192(a).

☒ Applicant's response to the final rejection, filed 1/2/97 has been considered with the following effect, but it is not deemed to place the application in condition for allowance:

1. ☐ The proposed amendments to the claim and/or specification will not be entered and the final rejection stands because:
- a. ☐ There is no convincing showing under 37 CFR 1.116(b) why the proposed amendment is necessary and was not earlier presented.
  - b. ☐ They raise new issues that would require further consideration and/or search. (See Note).
  - c. ☐ They raise the issue of new matter. (See Note).
  - d. ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.
  - e. ☐ They present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

2. ☐ Newly proposed or amended claims \_\_\_\_\_ would be allowed if submitted in a separately filed amendment cancelling the non-allowable claims.

3. ☒ Upon the filing an appeal, the proposed amendment ☐ will be entered ☐ will not be entered and the status of the claims will be as follows:

Claims allowed: NONE  
Claims objected to: NONE  
Claims rejected: 1-15

However;

☐ Applicant's response has overcome the following rejection(s): \_\_\_\_\_

4. ☒ The affidavit, exhibit or request for reconsideration has been considered but does not overcome the rejection because of the reasons stated in the Final Rejection and the attached reasons.

5. ☐ The affidavit or exhibit will not be considered because applicant has not shown good and sufficient reasons why it was not earlier presented.

☐ The proposed drawing correction ☐ has ☐ has not been approved by the examiner.

☒ Other See Attachment

*Patrick Niland*  
PATRICK NILAND  
PATENT EXAMINER  
ART UNIT 1511

Art Unit: 1511

A. The applicant's argue that the instantly claimed polyethylene-vinyl alcohol copolymer and that of the cited prior art is not water swellable. The applicant's present a declaration on 1/6/96, by Michael Jones. The declaration states that polyethylene vinyl alcohol copolymer pellets of 48 mole percent ethylene and presumably 52 mole percent vinyl alcohol immersed in saline water for 13.25 hours do not swell. This declaration is not persuasive for the following reasons.

1. The instant claims encompass the use of up to 75 mole percent vinyl alcohol (claim 2), which will be more hydrophilic than the copolymer of the declaration and Tanabe uses 67 mole % vinyl alcohol (column 12, lines 22-28). The declaration is therefore not commensurate in scope with the cited prior art and the instant claims.

2. The Jones declaration apparently puts preformed pellets of polyethylene vinyl alcohol copolymer in saline water. The polyethylene vinyl alcohol copolymer were apparently purchased as pellets. Often polymer is extruded and cut into pellets. In such processes, a waxy lubricant is used to ease in processing the polymer. It is not clear if such a lubricant is used in the declaration's polyethylene vinyl alcohol copolymer pellets. However, if such a lubricant was used, was hydrophobic, and coated the surface of the pellets, this would impede swellability.

and

3. During the interview of 10/17/96, the examiner injected a solution of the instantly claimed copolymer composition into water. See the Interview Summary of 10/17/96.

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The resulting blob of composition which formed was set upon a paper towel for several minutes. Upon being informed of the information of the instant declaration and knowing the hydrophilicity of vinyl alcohol polymer, evidenced by column 9, lines 3-9 of Okada et al., the examiner squeezed the blob of composition and a large amount of liquid came out. Upon initially injecting the composition into water, there were visible signs of the DMSO dissolving into the water. The applicant present at the interview pointed this out specifically. The applicant stated that the liquid squeezed out of the blob of composition might be residual DMSO. However, there was a very large amount of liquid relative to the blob injected into the water and surely not all of the liquid in the blob was squeezed out of the blob. The solution of polyethylene vinyl alcohol in DMSO would be considered to be extremely swollen. The DMSO and water appeared very miscible, as would have been expected. Thus, the combination of osmotic pressure, the openings left in the polymer matrix from it being swollen or dissolved with DMSO, and the fact that at least some of the DMSO clearly left the polymer matrix would have led one to expect that water had leached into the polymeric blob. Chemical analysis is clearly required to be sure that there was water in the blob. It is clear however, that the ability of a solution of polyethylene vinyl alcohol in DMSO would have been expected to be affected by water differently than a pellet of the polymer. For this reason, the applicant's declaration is not commensurate in scope with the instant claims and the cited prior art and is therefore not persuasive.

*H<sub>2</sub>O in pores.*

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The examiner notes that the arguments presented in past office actions are stronger if the polyethylene vinyl alcohol copolymer is not swellable in water. In this case, the water soluble dye of the secondary reference could only have been affected at the surface of the polymer composition. The fact remains that solid, water insoluble, inorganic particles of X-ray opaque pigments would still not have been expected to be affected by the water or blood, as reasoned in the example citing pigmented paint used on housing exteriors previously mentioned.

Tanabe et al., column 11, lines 50-53 discloses the use of X-ray contrast medium generically and the secondary references show the instantly claimed pigments to be such X-ray contrast medium and that these compounds are biocompatible.

The applicant has demonstrated no unexpected results stemming from the instantly claimed X-ray contrast medium. This rejection is therefore maintained for the reasons stated in the final rejection and above.

B. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick Niland on Monday to Friday from 9:30 to 6:00 whose telephone number is (703) 308-3510. If the examiner cannot be reached and the inquiry is urgent, call Paul Michl at (703) 308-2451. Direct any faxes to members of Art Unit 1511 to (703) 305-5433.

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January 16, 1997

A handwritten signature in cursive script, reading "Patrick Niland".

Patrick Niland  
Patent Examiner  
Art Unit 1511